General

Guideline Title

Guideline for care of the patient receiving moderate sedation/analgesia.

Bibliographic Source(s)

Ogg MJ. Guideline for care of the patient receiving moderate sedation/analgesia. In: 2015 Guidelines for Perioperative Practice. Denver (CO): Association of periOperative Registered Nurses (AORN); 2015 Dec. p. e59-e90. [313 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 14, 2016 – General anesthetic and sedation drugs : The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.
- August 31, 2016 – Opioid pain and cough medicines combined with benzodiazepines : A U.S. Food and Drug Administration (FDA) review has found that the growing combined used of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. FDA is adding Boxed Warnings to the drug labeling of prescription opioid pain and prescription opioid cough medicines and benzodiazepines.
- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

Note from the Association of periOperative Nurses (AORN): This document provides guidance for care of the patient receiving moderate sedation/analgesia provided by a registered nurse (RN) in the perioperative practice setting. Guidance is provided for determining the scope of nursing practice related to administration of moderate sedation/analgesia, patient selection criteria, pre-sedation patient assessment (e.g., airway, difficult mask ventilation, obstructive sleep apnea), intraoperative sedation assessment, staffing, monitoring, medication administration, and postoperative discharge criteria.

I. The perioperative RN administering moderate sedation/analgesia must practice within the scope of nursing practice as defined by his or her state board of nursing and should comply with state advisory opinions, declaratory rules, and other regulations that direct the practice of the registered nurse.
II. The perioperative RN should perform and document a patient nursing assessment before administering moderate sedation/analgesia.
III. The perioperative RN administering moderate sedation/analgesia should continuously care for the patient throughout the procedure.
IV. The perioperative RN should know the recommended dose, recommended dilution, onset, duration, effects, potential adverse reactions, drug compatibility, and contraindications for each medication used during moderate sedation (see Guideline for medication safety. In: *Guidelines for Perioperative Practice*. Denver [CO]: AORN; 2015. pp. 291-334).
V. The perioperative RN should evaluate the patient for discharge readiness based on specific discharge criteria.
VI. The health care organization should provide the perioperative RN with initial and ongoing education and competency verification on his or her understanding of the principles and performance of the skills related to nursing care of the patient receiving moderate sedation/analgesia.
VII. The health care organization's interdisciplinary team should develop moderate sedation/analgesia policies and procedures based on the state's medical and nurse practice acts, regulatory requirements, practice guidelines, professional organizations' statements, and accreditation requirements.
VIII. Perioperative personnel should participate in quality assurance and performance improvement activities that are consistent with the health care organization's plan to improve understanding of and compliance with the principles and skills of moderate sedation/analgesia administration.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Any condition requiring diagnostic or therapeutic invasive or surgical procedures for which moderate sedation/analgesia is indicated
- Pain and anxiety associated with surgical or invasive procedures

Guideline Category

Management

Prevention

Risk Assessment

Clinical Specialty

Nursing

Surgery

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Guideline Objective(s)

- To provide guidance for care of the patient receiving moderate sedation/analgesia provided by a registered nurse (RN) in the perioperative practice setting
- To provide guidance for determining the scope of nursing practice related to administration of moderate sedation/analgesia, patient selection criteria, pre-sedation patient assessment (e.g., airway, difficult mask ventilation, obstructive sleep apnea), intraoperative sedation assessment, staffing, monitoring, medication administration, and postoperative discharge criteria

Target Population

Patients receiving moderate sedation/analgesia in the perioperative practice setting

Interventions and Practices Considered

1. Administration of moderate sedation/analgesia within the state's scope of nursing practice
2. Performance and documentation of a patient nursing assessment before administering moderate sedation/analgesia
3. Provision of continuous care for the patient throughout the procedure
4. Ensuring healthcare personnel's knowledge of each medication used during moderate sedation
5. Evaluating the patient for discharge readiness based on specific discharge criteria
6. Providing the perioperative registered nurse (RN) education and competency verification on skills related to nursing care of the patient receiving moderate sedation/analgesia
7. Development of moderate sedation/analgesia policies and procedures based on the state's medical and nurse practice acts, regulatory requirements, practice guidelines, professional organizations' statements, and accreditation requirements
8. Participation in quality assurance and performance improvement activities

Major Outcomes Considered

- Depth of sedation
- Recovery time
- Pain perception
- Patient satisfaction
- Adverse events and complications related to sedation

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Evidence Review

A medical librarian conducted systematic searches of the databases MEDLINE®, CINAHL®, and the Cochrane Database of Systematic Reviews in April 2013 and November 2014, and limited results to meta-analyses, systematic reviews, randomized and nonrandomized trials and studies, reviews, and guidelines. The librarian also conducted a non-systematic search of the Scopus® database. The searches were limited to literature published in English between 2006 and November 2014. At the time of the initial searches, the librarian established weekly alerts on the search topics and until April 2015, presented relevant alert results to the lead author.

During the development of this guideline, the lead author requested supplementary literature searches and additional literature that either did not fit the original search criteria or was discovered during the evidence-appraisal process. Finally, the lead author and the medical librarian identified relevant guidelines from government agencies, professional organizations, and standards-setting bodies.

Although the lead author's original search request encompassed both moderate sedation and local anesthesia, only literature relevant to the care of patients receiving moderate sedation/analgesia was considered for inclusion in this document. Search terms included *conscious sedation, anti-anxiety agents, flumazenil, naloxone, propofol, midazolam, fentanyl, drug hypersensitivity, risk assessment, sleep apnea syndromes, continuous positive airway pressure, modified Mallampati test, thyromental distance test, bispectral index, airway management,* and *patient discharge*. Other key words were included to address the concepts of patient assessment, sedation scales, risk factors, patient monitoring, and tools and methods for predicting difficult mask ventilation. The complete search strategies are available upon request.

Inclusion criteria were research and non-research literature in English, complete publications, relevance to the key questions, and publication dates within the time restriction unless none was available.

Excluded were non-peer-reviewed publications and literature that examined local anesthesia, local monitored anesthesia care, general anesthesia, regional anesthesia (e.g., spinal, epidural), total intravenous anesthesia, minimal sedation, deep sedation, endotracheal intubation, laryngoscopy, awake intubation, dental office procedures, fospropofol, etomidate, propofol administration in the emergency room and intensive care unit, sedation for intubated and mechanically ventilated patients, palliative care, premedication for general anesthesia, pain management following discharge from the post-anesthesia care unit (PACU), and proceduralist techniques. Low-quality evidence was excluded when higher quality evidence was available, and literature outside the time restriction was excluded when literature within the time restriction was available.

Number of Source Documents

In total, 1,222 research and non-research sources of evidence were identified for possible inclusion; 314 full-text sources were cited in the guideline. See Figure 1 in the original guideline document for a flow diagram of literature search results.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

I: Randomized controlled trial (RCT) or experimental study, systematic review of all RCTs

II: Quasi-experimental study, systematic review of quasi-experimental studies or combination of quasi-experimental and RCTs

III: Non-experimental studies, qualitative studies, systematic review of non-experimental studies, combination of non-experimental, quasi-experimental, and RCTs, or any or all studies are qualitative

IV: Clinical practice guidelines, position or consensus statements

V: Literature review, expert opinion, case report, community standard, clinician experience, consumer experience, organizational experience (quality improvement, financial)

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Articles identified in the search were provided to the project team for evaluation. The team consisted of the lead author and three evidence appraisers. The lead author divided the search results into topics and assigned members of the team to review and critically appraise each article using the Association of periOperative Registered Nurses (AORN) Research or Non-Research Evidence Appraisal Tools as appropriate. The literature was independently evaluated and appraised according to the strength and quality of the evidence. Each article was then assigned an appraisal score. The appraisal score is noted in brackets after each reference, as applicable, in the original guideline document.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The collective evidence supporting each intervention within a specific recommendation was summarized, and the Association of periOperative Registered Nurses (AORN) Evidence-Rating Model (see the "Rating Scheme for the Strength of the Recommendations" field) was used to rate the strength of the evidence. Factors considered in the review of the collective evidence were the quality of evidence, the quantity of similar evidence on a given topic, and the consistency of evidence supporting a recommendation. The evidence rating is noted in brackets after each intervention in the original guideline document.

Rating Scheme for the Strength of the Recommendations

1: Strong Evidence: Interventions or activities for which effectiveness has been demonstrated by high quality evidence from rigorously-designed studies, meta-analyses, or systematic reviews, or rigorously-developed clinical practice guidelines

- Evidence from a meta-analysis or systematic review of research studies that incorporated evidence appraisal and synthesis of the evidence in the analysis
- Supportive evidence from a single well-conducted randomized controlled trial (RCT)
- Guidelines that are developed by a panel of experts, that derive from an explicit literature search methodology, and include evidence appraisal and synthesis of the evidence

1: Regulatory Requirement: Federal law or regulation

2: High Evidence: Interventions or activities for which effectiveness has been demonstrated by evidence from:

- Good quality systematic review of RCTs
- High quality systematic review in which all studies are quasi-experimental or a combination of RCTs and quasi-experimental studies
- High quality quasi-experimental study
- High quality systematic review in which all studies are non-experimental or include a combination of RCTs, quasi-experimental, and non-experimental studies. Any or all studies may be qualitative.
- High quality non-experimental studies
- High quality qualitative studies
- Good quality clinical practice guideline, consensus or position statement

3: Moderate Evidence: Interventions or activities for which the evidence is has been demonstrated by evidence from:

- Good quality systematic review in which all studies are quasi-experimental or a combination of RCTs and quasi-experimental studies
- Good quality quasi-experimental study

- High or good quality literature review, case report, expert opinion, or organizational experience

4: Limited Evidence: Interventions or activities for which there are currently insufficient evidence or evidence of low quality

- Supportive evidence from a poorly conducted research study
- Evidence from non-experimental studies with high potential for bias
- Guidelines developed largely by consensus or expert opinion
- Non-research evidence with insufficient evidence or inconsistent results
- Conflicting evidence, but where the preponderance of the evidence supports the recommendation

5: Benefits Balanced with Harms: Selected interventions or activities for which the Association of periOperative Registered Nurses (AORN) Guidelines Advisory Board is of the opinion that the desirable effects of following this recommendation outweigh the harms

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The Guideline for Care of the Patient Receiving Moderate Sedation/Analgesia has been approved by the Association of periOperative Registered Nurses (AORN) Guidelines Advisory Board. It was presented as a proposed guideline for comments by members and others. The guideline is effective December 15, 2015.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The literature was independently evaluated and appraised by the lead author and the evidence reviewer according to the strength and quality of the evidence. Each article was then assigned an appraisal score determined by consensus. The appraisal score is noted in brackets after each reference in the original guideline document, as applicable. Also see the original guideline document for the systematic review and discussion of evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- The patient undergoing surgery or other invasive procedure with moderate sedation/analgesia will experience minimal pain and anxiety. Moderate sedation also can facilitate cooperation between the patient and care providers.
- Early recognition and management of cardiac or respiratory depression may prevent hypoxic brain damage, cardiac arrest, or death.
- Refer to the original guideline document for additional discussion of potential benefits of specific interventions.

Potential Harms

- Harms related to moderate sedation/analgesia medication include complications associated with the respiratory system (e.g., hypoxia,

hypercapnia, impaired airway reflexes, loss of airway patency, airway obstruction, respiratory depression) and cardiovascular system (e.g., hypotension, cardiac arrhythmias).
- The primary causes of morbidity associated with moderate sedation are drug-induced respiratory depression and airway obstruction.
- Refer to the original guideline document for additional discussion of potential harms of specific interventions.

Contraindications

Contraindications

Moderate sedation/analgesia provided by a registered nurse (RN) may be contraindicated and need referral to a higher level of care with an anesthesia professional when the patient presents with any of the following:

- Known history of respiratory or hemodynamic instability
- History of coagulation abnormality
- History of neurologic or cardiac disease that may be affected by medications administered for moderate sedation/analgesia
- History of renal or liver disease that may affect metabolism of medications administered for moderate sedation/analgesia
- Previous difficulties with anesthesia or sedation
- Severe sleep apnea or other airway related issues
- One or more significant comorbidities
- Pregnancy
- Inability to communicate (e.g., aphasic)
- Inability to cooperate
- Multiple drug allergies
- Multiple medications with potential for drug interaction with sedative analgesics
- Current substance abuse (e.g., street drugs, alcohol, non-prescribed prescription drugs)
- American Society of Anesthesiologists (ASA) physical status classification of unstable ASA III
- ASA physical status classification of ASA IV or above

Qualifying Statements

Qualifying Statements

- These recommendations represent the Association's official position on questions regarding optimal perioperative nursing practice.
- No attempt has been made to gain consensus among users, manufacturers, and consumers of any material or product.
- Compliance with the Association of periOperative Registered Nurses (AORN) guideline is voluntary.
- AORN's recommendations are intended as achievable and represent what is believed to be an optimal level of patient care within surgical and invasive procedure setting.
- Although they are considered to represent the optimal level of practice, variations in practice settings and clinical situations may limit the degree to which each recommendation can be implemented.
- It is not the intent of this guideline to address situations that require the services of an anesthesia professional or to substitute the services of a perioperative registered nurse (RN) in those situations that require the services of an anesthesia professional.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Dec

Guideline Developer(s)

Association of periOperative Registered Nurses - Professional Association

Source(s) of Funding

Association of periOperative Registered Nurses (AORN)

Guideline Committee

Association of periOperative Registered Nurses (AORN) Guidelines Advisory Board

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Financial Disclosures/Conflicts of Interest

No financial relationships relevant to the content of this guideline have been disclosed by the authors, planners, peer reviewers, or staff.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available to subscribers from the Association of periOperative Nurses Web (AORN) site .

Print copies: Available for purchase from the AORN Web site .

Availability of Companion Documents

The following is available:

- Guideline for care of the patient receiving moderate sedation/analgesia evidence table. 2015. 37 p. Available from the Association of periOperative Nurses (AORN) Web site .

Additional implementation tools, including clinical FAQs, online learning modules, videos and community discussions are available from the AORN Web site .

Documents related to the evidence rating model, hierarchy of evidence, and expanded appraisal tools are available from the AORN Web site .

In addition, an AORN Guidelines for Perioperative Practice eBook mobile app is available from the AORN Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on February 17, 2016. The information was verified by the guideline developer on March 30, 2016. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on opioid pain medicines. This summary was updated by ECRI Institute on October 21, 2016 following the U.S. Food and Drug Administration advisory on opioid pain and cough medicines combined with benzodiazepines. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

Copyright Statement

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